

REMARKS

The amendments to claims 1, 6 and 10 are supported by these claims as originally filed, the amendments rearranging subject matter originally present in the claims. Claims 38-40 were objected to as being dependent upon a rejected base claim, the Office stating that they would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This has been done and allowance of claims 38-40 is requested. Entry of the amendments and reconsideration of the claims in view of the following remarks are respectfully requested.

The Office Action mailed July 20, 2007 has been carefully reviewed, and the instant amendments and remarks are provided in response thereto.

Claims 1, 5 and 41 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Goodman et al.* (U.S. 5,109,849, hereinafter "*Goodman*"). In explaining the basis for the rejection over *Goodman*, the Office alleges that *Goodman* discloses the elements of claim 1, each element being recited, followed by a reference to Column 7, lines 39-50; Column 8, lines 4-8; and Column 12, lines 27-30. This rejection is traversed.

Goodman, like *Hirsch* which was addressed in the prior Office Action and response and is also relied on in part herein, describes an apparatus that is specifically designed to allow an internal electrode to make contact with the skin surface of an individual, specifically a fetus, when the apparatus is placed on the skin surface. To accomplish this, *Goodman*, like *Hirsch*, describes a device wherein the sensor probe has a deformable seal which is made of a material having a compliancy greater than the compliancy of fetal tissue so that when suction is applied, the wall of the sensor deforms without injuring the sensitive fetal tissue, allowing an internal light source and

light detector as well as an electrocardiogram (ECG) sensor to be drawn down onto the fetus' skin to make the required contact. (See, e.g., claim 1) In contrast, the apparatus and methods of the instant invention are not directed to making contact with the skin surface directly through an electrical contact that is drawn down to the skin, but rather through "an electroconductive medium" which is a required element of the claims. This feature is absent from *Goodman* as it was from *Hirsch*. Furthermore, the *Goodman* sensor system, wherein the light source and detector and ECG electrode merely make contact with the surface of the skin, cannot be used for determining the transepithelial condition of tissue.

Column 7 of *Goodman* relied on by the Office discloses the use of vacuum in the *Goodman* sensor. It is initially noted that the *Goodman* sensor is used for measuring fetal blood flow characteristics *in utero* and that the sensor is designed to be securely affixed to a surface skin portion of a fetus. The lines in Column 7 cited by the Office include disclosure of the use of both a vacuum tube and vent tube connected to the sensor. The vent tube is disclosed as needed in order to allow air to pass through the sensor cavity in order to avoid the sensor becoming clogged by "fluids and solid matter drawn into the vacuum tube." (Column 7, lines 53-54) Taking into consideration the overall construction of the *Goodman* sensor and the use of a combination of vacuum and vent tubes, it should be apparent that this disclosure does not correspond to the elements of claim 1 of the present invention.

The Office next refers to Column 8, lines 4-8, which states:

"In an alternative embodiment, humid air or a saline solution may be suctioned from a source connected to vent tube 136, through cavity 106 and into vacuum tube 134, to maintain a flow of liquid through cavity 106

for moistening the fetal tissue surface under probe
100."

(*Id.*)

The Office equates this disclosure with Applicant's claim element relating to the use of an electroconductive medium; such reliance is misplaced. To begin with, it is apparent that the use of "humid air" is irrelevant to Applicant's claim. Furthermore, even the reference to the use of "saline solution" does not equate with Applicant's claim element since the flow of liquid required by *Goodman* is stated to be only sufficient to provide moistening of the fetal tissue under the probe and therefore is not necessarily sufficient to establish an electrical connection between an electrode and the underlying tissue. It is accepted that the mere possibility that a description in reference may relate to the claim is not sufficient to be anticipatory under 35 U.S.C. § 102(b).

Finally, the Office refers to Column 12, lines 27-30. It is noted that this portion of *Goodman* discloses the use of a "fetal ECG electrode." The cited portion discloses that with the probe in place, the electrode "contacts the fetal tissue." Furthermore, it is stated that the electrode is mounted in such a manner as to "serve the dual purpose of preventing light from shunting between the light sources and the photodetector, and of providing a conductive surface useful as an ECG sensor." (*Id.*) In both this portion cited by the Office as well as throughout the disclosure of *Goodman*, reference is made solely to an "ECG sensor." There is no teaching or suggestion in *Goodman* regarding the use of "a current-passing electrode" as required by the instant claims. Taking into consideration the full disclosure of *Goodman* regarding the use of an ECG sensor, it is clear that this feature does not correspond to the current-passing electrode used in combination with an electroconductive medium as described in the instant claims.

Finally, it is noted that the fetal sensor of *Goodman* is not "an apparatus for determining the condition of a region of tissue" as set forth in the instant claims. The *Goodman* sensor measures characteristics of the fetus overall rather than determining the condition of a region of tissue. This distinction has been emphasized by the claim amendments submitted herein.

Thus, the amended claims cannot be anticipated under 35 U.S.C. § 102(b) and withdrawal of this aspect of the rejection is respectfully requested.

Claims 6-10, 42 and 43 are rejected under 35 U.S.C. § 102(e) as being anticipated by *Schulze et al.* (U.S. 7,223,239, hereinafter "*Schulze*"). Again the Office refers to the elements of the instant claims, including "an electroconductive medium disposed within the interior" of the device and "a measuring device in communication with the electrode operable to determine an electrical signal from the electrode", alleging they are disclosed in *Schulze*. The statement by the Office concludes with a reference to Column 5, lines 60-66; Column 6, lines 34-41; and Column 11, lines 34-41. This rejection is traversed.

Initially it is noted that the medical device disclosed in *Schulze* is one for use "on a bodily organ of a patient" wherein "an energy transfer element" is used to, for example, introduce ultrasonic energy for the purposes of ablating a portion of the organ. It is also noted that the *Schulze* device provides for the use of a "fluid management system for circulating a fluid inside of the enclosed space." (*Id.*, claims 1-3) Clearly, the medical device disclosed in *Schulze* bears no relationship to the apparatus of the current claims. That being said, the following are comments that relate specifically to the basis for the rejection in view of *Schulze* set forth by the Office.

To begin with, the *Schulze* reference does not disclose an electroconductive medium disposed within the interior of its medical device. The *Schulze* fluid "acoustically couples the energy transfer element to the bodily organ, and the fluid also cools the energy transfer element." (Column 3, lines 9-11) These functions and the fluids that can be used for such purposes are not necessarily the "electroconductive medium" required by the instant claims. Again, the mere possibility that such fluids may be similar is not a sufficient basis for anticipating the claims under 35 U.S.C. § 102(b).

The Office also refers to "a measuring device in communication with the electrode operable to determine an electrical signal from the electrode." This too is incorrect, as *Schulze* merely describes the various electrical connections that can be made to an energy transfer element within the medical device, the element being used to develop intense ultrasonic energy. There is nothing in *Schulze* that corresponds to the application of an electrical signal through an electrode and the measurement of an electrical response thereto. The portion of *Schulze* cited at Column 6, lines 34-41, refers merely to an ultrasonic transducer control system for use with the medical device.

The portion relied on by the Office at Column 11, lines 34-41, is a generic disclosure that the medical device disclosed in *Schulze* "may be useful for the administration of pharmaceutical agents or for the removal of fluids, toxins, or other substances from the patient." *Schulze* then continues, "The present invention may be used for internal surgical procedures on various organs including the liver, stomach, and lungs, or may also be used externally and attached to the patient's skin to treat or diagnose underlying tissues." Such generic disclosure is not consistent with the elements of claims 6-10, 42 and 43 of the instant invention. Note in particular

that *Schulze* does not disclose what elements or features of its medical device can be used for the various purposes described at Column 11 and which elements or features should be ignored. This is particularly relevant since *Schulze* refers to both the administration of various substances as well as to the use for surgical procedures and skin surface measurements. Finally, it fails to even generally disclose an apparatus suitable for determining the condition of a region of tissue. In conclusion, *Schulze* does not correspond to the specific elements of the instant claims, and withdrawal of this aspect of the rejection is respectfully requested.

Claims 2 and 3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Goodman* as applied to claim 1 above, and further in view of *Hirsch et al.* (U.S. 5,345,935, hereinafter "*Hirsch*"). This rejection is traversed.

The Office explains that *Goodman* fails to disclose that the suction source can be a syringe or an aspirator. *Hirsch* is said to disclose the use of suction in a medical probe based on the use of a syringe or an aspirator; Figures 6-11 of *Hirsch* are identified. The Office explains that it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the vacuum means in *Goodman* to include the use of a syringe or aspirator since these devices were well known vacuum sources.

The Office suggests that the substitution of a syringe or aspirator for the controlled vacuum pump system in *Goodman* can be made merely because such devices were known. However, the sensor system described in *Goodman* is one that is designed to avoid disfigurement or damage to fetal tissue surfaces; see, for example, Column 2, lines 33-38, wherein it is disclosed that such damage may occur if vacuum attachment is made with heavy vacuum suction. Furthermore, the sensor system of *Goodman* includes the use of a deformable seal on the sensor having a

"compliance greater than the compliance of fetal tissue" (claim 1) such that deformation of the seal does not damage the tissue." Consequently, as noted by the Office, even though alternative means of vacuum such as by the use of an aspirator or syringe were known at the time of the *Goodman* invention, such means were not included by *Goodman*. It is reasonable to conclude that such alternatives were not disclosed as useful because the *Goodman* system required a more controlled alternative method for applying vacuum in order to avoid damage to delicate fetal tissue. Thus, considering both the *Goodman* invention as well as the instant invention, the indiscriminate substitution of elements from *Hirsch* by the Office merely because they existed finds no reasonable basis or support in the primary reference, *Goodman*. Withdrawal of this aspect of the rejection is respectfully requested.

Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Schulze* as applied previously to claim 10 and further in view of *Dempsey et al.* (U.S. 5,417,222, hereinafter "*Dempsey*"). This rejection is traversed.

The Office refers to the earlier discussion relating to the elements of *Schulze* and acknowledges that *Schulze* fails to disclose that the measuring device or displaying device is in communication with the electrode by wireless connections.

Dempsey is said to disclose wireless communication systems for patient monitoring and measuring devices in communication with an electrode. The Office concludes that it would have been obvious to modify the means of *Schulze* to include the use of wireless connections pursuant to the teachings of *Dempsey* since "it is well known in the art to substitute a wireless connection for a wired connection in medical applications." (Office Action, page 5)

Although *Dempsey* may address the use of a wireless communications system, *Dempsey* does not cure any of the

deficiencies of *Schulze* as discussed in detail above. Consequently, since claims 11 and 12 depend from claim 10, which is distinguished over *Schulze* for the reasons discussed above, the combination of *Schulze* and *Dempsey* does not render these claims obvious.

Furthermore, it is noted that the electrical connections required by *Schulze* are needed in order to maintain electrical contact with the intense ultrasonic energy generating element and therefore there is no reasonable basis to convert direct electrical connections for the purposes in *Schulze* since they are required in order to maintain and generate energy for the ablation device. Finally, since *Schulze* does not disclose or require the measurement of electrical properties of the underlying tissue, there is again no basis on which to conclude that wireless communications would serve any useful function. Withdrawal of this aspect of the rejection is respectfully requested.

Claim 37 is rejected under 35 U.S.C. § 103(a) as being unpatentable over *Goodman* as applied to claim 1 and further in view of *Schulze*. This rejection is traversed.

The Office explains that *Goodman* discloses a sensing device but fails to disclose the use of a pharmacological agent in combination with the electroconductive medium. *Schulze* is said to disclose a means for applying a device to a tissue and further discloses the use of a pharmacological agent in combination with the electroconductive medium. (Column 9, lines 42-45) The Office concludes that it would have been obvious to one of ordinary skill in the art to "modify the medium of *Goodman* to include the use of a pharmacological agent as per the teachings of *Schulze*, since it would provide a means of applying a therapy to the measurement site." This analysis is traversed.

To begin with, it is useful to consider not only the portion of *Schulze* cited by the Office but the adjoining subject matter in order to put the portion relied on in proper context:

"Variation of the hydraulic vacuum pressure also allows adjustment of the distance between face 403 of energy transfer element 402 and organ 12. Embodiment 400 allows the operator the option of using a fluid media for fluid 108 that the operator prefers not to spill onto organ 12 and into the body cavity. This primarily helps to conserve fluid 108 (which may contain, for example, expensive therapeutic agents) and minimizes the need for aspirating fluid from the body cavity during the procedure."

(Column 9, lines 37-45)

To begin with, the use of a pharmacologic agent in combination with *Goodman* in order to apply therapy to the measurement site of *Goodman* is totally inconsistent with the stated objectives and methods disclosed in *Goodman*, namely, the measurement of oxygen levels and electrocardiogram measurements at the skin surface of a fetus *in utero*. There is nothing in *Goodman* that would suggest the use of any pharmacological or therapeutic agent, nor would such use be appropriate since there are no means of introducing such agents to the fetus.

Additionally, as discussed above, there is no basis in *Schulze* to equate the properties of the ultrasonic coupling fluid with the requirements of an electroconductive medium as in the present claims. Furthermore, the brief, passing reference to a "therapeutic agent" in *Schulze* similarly does not provide that such an agent be an electroconductive medium. Consequently, the combination of the fluid and possible therapeutic agent in *Schulze* does not result in an electroconductive medium as required by the instant claims.

Overall, even if the combination suggested by the Office were to be made, it does not reach the elements set forth in instant claim 37. Withdrawal of this aspect of the rejection is respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: January 18, 2008

Respectfully submitted,

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